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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,701

09/01/2005

Arnold I Levinson

UPN0030.100

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34136

7590

08/13/2008

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

08/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,701	Applicant(s) LEVINSON ET AL.	
	Examiner Michael Szperka	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,22-24,26-29 and 32-49 is/are pending in the application.
- 4a) Of the above claim(s) 9,10 and 38-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,22-24,26-29 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/17/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendments received May 27, 2008 are acknowledged.

Claims 4, 11-21, 25, 30, and 31 have been canceled.

Claims 1-3, 5-10, 22-24, 26 have been amended.

Claims 32-49 have been added.

Claims 1-3, 5-10, 22-24, 26-29, and 32-49 are pending.

Applicant's election with traverse of Group I, claims 1-3, 5-8, 22-24, 26-29, and 33-37, drawn to nucleic acids, vectors and host cells in the reply filed on May 27, 2008 is acknowledged. The traversal is on the ground(s) that the restriction between Group I (products) and Group II (methods of administering products) is improper because there is no search burden. This is not found persuasive because search burden is not a consideration in making a lack of unity of invention determination. Further, even if burden was a consideration, burden is not limited to searching the product in the prior art since products and methods raise distinct issues under all statutes, such as prior art, obviousness, enablement, and written description. Consideration of these distinct issues does constitute additional burden. Finally, given that the pending claims are related as product and method of using said product, Applicant is reminded of the possibility of rejoinder upon indication of allowability of all pending product claims as was indicated in paragraph 6 of the restriction requirement mailed 11/26/07. Note that applicant's traversal is limited only to the restriction between groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9, 10, and 38-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 27, 2008.

Claims 1-3, 5-8, 22-24, 26-29, and 32-37 are under examination in the instant office action.

Information Disclosure Statement

2. The IDS received 6/17/05 is acknowledged and has been considered.

Claim Objections

3. Claims 5 and 35 are objected to because of minor informalities. Specifically, periods should appear only at the end of sentences and as such appropriate correction is required in claims 5 and 35.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5-8, 22-24, 26-29, and 32-27 are rejected under 35 U.S.C. 102(a and e) as being anticipated by WO 02/20038.

The '038 document discloses nucleic acid molecules comprising the membrane anchoring region of B-cell bound IgE linked to a foreign T helper epitope (see entire document, particularly the abstract and pages 37 and 41). Helper T epitopes are disclosed as coming from tetanus toxoid (see particularly page 30). These nucleic acids are further disclosed as being present in plasmids and viral vectors for use in vaccines

comprising excipients (see particularly paragraphs 52-56 and 66-67). The nucleic acids of the '038 document are also disclosed as being present in bacterial and mammalian cells for use in production of recombinant polypeptides (see particularly pages 60-66).

Therefore, the prior art anticipates the claimed invention.

6. Claims 1-3, 5-8, 22-24, 26-29, and 32-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Klysner et al. (US2002/0172673).

Klysner et al. disclose nucleic acid molecules comprising the membrane anchoring region of B-cell bound IgE linked to a foreign T helper epitope (see entire document, particularly the abstract and paragraphs 121 and 132). Helper T epitopes are disclosed as coming from tetanus toxoid (see particularly paragraph 101). These nucleic acids are further disclosed as being present in plasmids and viral vectors for use in vaccines comprising excipients (see particularly paragraphs 171- 180 and 214-219). The nucleic acids of Klysner et al. are also disclosed as being present in bacterial and mammalian cells for use in production of recombinant polypeptides (see particularly paragraphs 198-213).

Therefore, the prior art anticipates the claimed invention.

7. Claims 1-3, 22-24, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (WO 98/53843).

Chen et al. disclose vaccine constructs comprising the membrane bound domain of IgE coupled to heterologous sequences and excipients (see entire document, particularly the abstract and pages 3-5). These constructs are disclosed as being made recombinantly using vectors and host cells (see page 5). Note that heterologous antigens comprise helper T epitopes.

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 5-8, 26, 27, 29, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (WO 98/53843) in view of Wang et al. (WO 99/67293) and in view of Hollis et al. (US 5,629,415).

The disclosure of Chen et al has been discussed above and differs from the instant invention in that the nucleic acids of Chen et al. are not disclosed as being administered to a patient (i.e. the nucleic acids are not disclosed as a vaccine).

Wang et al. disclose vaccine constructs wherein IgE sequence is coupled to T helper epitopes such as those from tetanus toxoid, wherein the administered construct is a nucleic acid (see entire document, particularly the abstract and pages 11, 13-14, 16, 20, 39-40).

Hollis et al. disclose that recombinant IgE encoding polynucleotides can be inserted in to plasmid vectors and used to generate a wide variety of host cells including bacterial and mammalian cells (see entire document, particularly columns 4-7). Such host cells can be used to express polypeptides, with antibodies specific for the IgE constructs being used for affinity purification of the expressed polypeptide (see column 7).

Therefore, it would have been obvious to a person of ordinary skill at the time the instant invention was made to use the nucleic acid constructs of Chen et al. in nucleic acid vaccines since the use of nucleic acid vaccines was well known and routine in the

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art as disclosed by Wang et al. Such vaccines could be propagated in bacterial host cells as disclosed by Hollis et al. due to their ease of manufacture.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
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